

CRITERIA FOR PRIOR AUTHORIZATION

Jadenu® (deferasirox)

PROVIDER GROUP Pharmacy**MANUAL GUIDELINES** The following drug requires prior authorization:
Deferasirox (Jadenu)**CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD:** (must meet all of the following)

- Patient must be ≥ 2 years old
- Patient must have a serum ferritin consistently $> 1,000$ mcg/L
- Patient must have been transfused with ≥ 100 mL/kg of packed red blood cells (e.g., at least 20 units of packed red blood cells for a 40-kg person)
- Dose must not exceed 28 mg per kg per day
- Patient must not be concurrently taking an aluminum-containing antacid preparation
- Patient must not be pregnant
- Patient must not have any of the following:
 - Serum creatinine > 2 times the age-appropriate upper limit of normal (ULN) or creatinine clearance less than 40 mL/min
 - Poor performance status
 - High-risk myelodysplastic syndromes (MDS)
 - Advanced malignancies
 - Platelet counts $< 50 \times 10^9/L$
 - Severe hepatic impairment (Child-Pugh class C)

LENGTH OF INITIAL APPROVAL: 3 months**RENEWAL CRITERIA FOR TRANSFUSIONAL IRON OVERLOAD:** (must meet all of the following)

- Serum ferritin is monitored monthly
- Serum ferritin is consistently > 500 mcg/L

LENGTH OF RENEWAL APPROVAL: 6 months**CRITERIA FOR NON-TRANSFUSIONAL IRON OVERLOAD:** (must meet all of the following)

- Patient must be ≥ 10 years old
- Patient must have a liver iron (Fe) concentration (LIC) ≥ 5 mg Fe/g dw (milligrams of iron per gram of liver dry weight)
- Patient must have a serum ferritin > 300 mcg/L
- Dose must not exceed 14 mg per kg per day
- Patient must not be concurrently taking an aluminum-containing antacid preparation
- Patient must not be pregnant
- Patient must not have any of the following:
 - Serum creatinine > 2 times the age-appropriate upper limit of normal (ULN) or creatinine clearance less than 40 mL/min
 - Poor performance status
 - High-risk myelodysplastic syndromes (MDS)
 - Advanced malignancies
 - Platelet counts $< 50 \times 10^9/L$
 - Severe hepatic impairment (Child-Pugh class C)

PA Criteria

RENEWAL CRITERIA FOR NON-TRANSFUSIONAL IRON OVERLOAD: (must meet all of the following)

- Serum ferritin is monitored monthly
- Serum ferritin > 300 mcg/L
- LIC is monitored every 6 months
- LIC > 3 mg Fe/g dw

LENGTH OF APPROVAL: 3 months

NOTES:

- Lower doses of Jadenu® are bio-equivalent to higher doses of Exjade®
 - Jadenu 90 mg is bioequivalent to Exjade 125 mg
 - Jadenu 180 mg is bioequivalent to Exjade 250 mg
 - Jadenu 360 mg is bioequivalent to Exjade 500 mg